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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,058	04/13/2004	Loretta Nielsen	016930-003714US	6094

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EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,058	NIELSEN ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *16 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 17-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, claims 2-15, 17-26 and 28-30 and linking claim 1, the further election of p53 and the species election of head and neck cancer, in the reply filed on November 14, 2005 is acknowledged. It is noted that applicant refers to the election of p53 as a species election. This is not a species, the restriction to a protein was a further restriction based on the lack of unity between the proteins recited in the Markush group in claim 5.

Claims 16 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 14, 2005.

Priority

Provisional applications 60/038065 and 60/047834 do not provide support for the term "adjunctive anti-cancer agent" and its definition as not including agents having DNA damaging activity, thus the priority date for the claimed invention is February 17, 1998, the filing date of application 09/024,932. If applicant believes support exists for this term in the provisional applications, such support should be pointed out with particularity in the response to this action.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademark "Apoptag" has been noted in this application (in example 3). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is recommended that the entire specification be reviewed for other instances where trademarks are used but not identified as such.

Appropriate correction is required.

Claim Objections

Claims 1, 5, 12, 14 and 24 are objected to because of the following informalities: each of these claims contains non-elected subject matter; specifically they recite a tumor suppressor protein. Appropriate correction is required.

Claims 8, 19, 24, 28 and 30 are objected to because of the following informalities: each of these claims is non-grammatical. Claims 8 and 19 recite "3500 bp for the 5' viral termini". It appears this claim should read "from the 5' viral termini". Claims 24, 28 and 30 are ungrammatical due to the article "a" or "an". For example, claim 24 recites "an exogenous a tumor suppressor nucleic acid". Appropriate correction is required.

Claim Rejections - 35 USC § 101 & § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26 and 28-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 28 depends from claim 24 and recites the composition is present in a mammal. The scope of claim 24 thus encompasses mammals, including humans. Claims 25, 26, 29 and 30 are rejected due to their dependence from claim 24.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims refers to "the 5' viral termini". These claims are indefinite because termini is the plural and indicates the virus has multiple 5' ends.

Claims 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims recites that the kit of the invention further comprises a deletion of a DNA sequence. Although this claim depends from a claim referring to deletion of protein IX DNA, it is unknown whether the further deletion is from the one recited in claims 8 and 19 or if the DNA is deleted from the tumor suppression gene. Additionally, the phrase "DNA sequence designated E1a and E1b" is indefinite because it is unknown what sequence is designated E1a and E1b.

Claims 24-26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 is indefinite because a proper composition claim contains at least two components while this claim recites only one, a mammalian cancer or hyperproliferative cell. Additionally, the metes and bounds of this claim cannot be determined because the components of the cell are not recited as a list separated by commas but contain both "and" and "or". Thus it is unknown what components are required to be contained in the cell and which are optional. Claims 25, 26 and 28-30 are indefinite due to their dependence from claim 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12-15, 17, 23-26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tocque (WO 96/22101) as evidenced by US 6,262,032.

The claims are directed to compositions, kits and mammalian cells that contain a tumor suppressor nucleic acid that is p53 and may be contained within an adenoviral vector and an anti-cancer agent that may be paclitaxel or a derivative.

The disclosure of Tocque is in French. US 6,262,032 is the national stage application of this disclosure and is a direct English translation of the foreign language disclosure. For convenience the disclosure of the English language document is cited. Tocque discloses at column 4, lines 35-41 a medicinal composition of a tumor suppressor gene and a taxoid and disclose p53 as a preferred tumor suppressor gene. At column 3, lines 62-67 and column 10, lines 37+ Tocque discloses that the nucleic acids are in vectors such as adenoviral vectors. At columns 8-10 Tocque discloses the structures of taxoids and at column 9, line 8 cites paclitaxel as a preferred taxoid. Tocque additionally claims a method of destroying hyperproliferative cells; see claims 1, 6 and 11. These claims disclose a cancerous cell comprising a vector encoding p53 and paclitaxel.

Thus, Tocque discloses all limitations of and anticipate claims 1-6, 12-15, 17, 23-26 and 28-30.

Claims 1, 2, 4-6, 12, 14, 15, 17, 24-26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Blagosklonny et al. (Int. J. Cancer 1996, cited on IDS).

The claims are directed to compositions, kits and mammalian cells that contain a tumor suppressor nucleic acid that is p53 and may be contained within an adenoviral vector and an anti-cancer agent.

Blagosklonny et al. disclose treatment of cancer cells including glioblastoma cells in vitro with an adenoviral vector encoding p53 followed by the anti-cancer drug vincristine. Thus, Blagosklonny et al. disclose a composition of a cancer cell having exogenous p53 and an anti-cancer adjunctive agent.

Thus, Blagosklonny et al. disclose all limitations of and anticipate claims 1, 2, 4-6, 12, 14, 15, 17, 24-26, 29 and 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (WO 95/11984, of record) and Kohn et al. (US 5,565,478).

The claims are directed to compositions, kits and mammalian cells that contain a tumor suppressor nucleic acid that is p53 and may be contained within an adenoviral vector and an anti-cancer agent that may be paclitaxel or a derivative. The adenoviral vector may have a deletion of sequences related to protein IX and/or E1a and E1b or may comprise the adenovirus type 2 major late promoter, the tripartite leader cDNA and human p53 cDNA and may be the vector designated A/C/N/53.

Gregory et al. teach adenovirus vectors that express p53 and compositions comprising these vectors for the purpose of treating cancer. Gregory et al. teach particular embodiments where the vectors are have deletions of the protein IX, E1a and E1b sequences, where the vector comprises the adenovirus type 2 major late promoter, the tripartite leader cDNA and human p53 cDNA and where the vector is A/C/N/53. Gregory et al. do not teach compositions comprising paclitaxel or a paclitaxel derivative.

Kohn et al. teach that paclitaxel is an antitumor drug and demonstrates its effectiveness in ovarian and breast cancer cells in combination with a signal transduction inhibitor.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Gregory et al. and Kohn et al. to produce a composition comprising a nucleic acid encoding tumor suppressor gene p53 and paclitaxel. A person of ordinary skill in the art would have been motivated to do so because Gregory et al. teach vectors encoding p53 that are useful in treating cancer and Kohn et al. teach compositions comprising paclitaxel for the purpose of treating cancer. Further, section 2144.06 of the MPEP states the following:

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

A person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Gregory et al. and Kohn et al. because each of their teachings are directed to the same purpose and each of them demonstrate that their individual teachings function for their intended purpose.

Thus, claims 1-15 and 17-23 would have been obvious, as a whole, at the time of invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
January 17, 2006

J.D. SCHULTZ, Ph.D.
PATENT EXAMINER

Continuation of Attachment(s) 6). Other: IDS of 6/7/04, 6/14/04 and 2/19/05.